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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,812	10/05/2001	Thomas Clement Barthel	CMS-012	6757

7590

06/23/2003

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EXAMINER

RAM, JOCELYN DEBRA

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/23/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/972,812

Applicant(s)

BARTHEL ET AL.

Examiner

Jocelyn D Ram

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 12 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Koyata (4,349,032). Koyata shows an elongate viewing assembly for use as part of an endoscope, comprising: a flexible main portion (3) bendable between a relaxed configuration and a strained configuration and carrying an imaging optical fiber (15) and an illumination optical fiber (col 2, lines 63-66); and a rigid distal portion (5) connected to the main portion and having a distal end (5a) that is offset laterally from the main portion at an acute angle (Fig. 1), wherein the main portion and distal portion are made of different materials (inherently, since the main portion is flexible and the distal portion is made of rigid plastic), including an eyepiece (2).

Claims 1-3, 6, 8, 11, 12, 24 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hake (4,893,613). Hake shows an elongate viewing assembly for use as part of an endoscope, comprising: a flexible main portion (14b, 14c) bendable between a

relaxed configuration and a strained configuration and carrying an imaging optical fiber and an illumination optical fiber (col 4, lines 3-7); and a distal portion (14a) connected to the main portion and having a distal end that is offset laterally from the main portion, as broadly as claimed (col 4, lines 27-30), wherein the distal portion is substantially rigid (col 4, lines 66-68), the main portion and distal portion are made of substantially similar materials, inherently including a handle, a light source, and an eyepiece (col 4, lines 7-11).

Claims 1-3, 5, 8, 9, 11, 12, 37, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Salerno (5,394,865). Salerno shows an elongate viewing assembly for use as part of an endoscope, comprising: a flexible main portion (14) bendable between a relaxed configuration and a strained configuration (col 3, lines 50-63), including a polymeric sheath (65), and carrying an imaging optical fiber (18) and an illumination optical fiber (22); and a distal portion connected to the main portion and having a distal end (16) that is offset laterally from the main portion (14), as broadly as claimed (Fig. 4), wherein the distal portion is substantially rigid (col 3, lines 63-68), and has a diameter in the range of 2-5 mm (col 3, lines 54-56 and 62-64), the main portion and distal portion are made of substantially similar materials, , wherein the distal portion has a distal tip (16) having a diameter greater than that of the distal portion (col 4, lines 57-60), further including a handle (12), a light source (32), and an eyepiece (60).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 10, 13-17 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koyata. Koyata shows all of the limitations of claims 4, 10, 13-17 and 25-29 except for the specific offset angle, offset distance, and radius of curvature. Since the instant invention does not show criticality of a specific angle or distance, and the invention of Koyata is capable of bending by operating the string means, it would have been obvious to one of ordinary skill in the art at the time of the invention to bend the flexible tube at any angle, radius and distance.

Regarding claim 10, Koyata discloses that the distal portion can be made of a rigid plastic. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to use an alternative material that has similar rigidity properties, such as a metal material. It is noted that the instant invention does not place any criticality on the composition of the material of the distal end except that it is rigid and suitable for use in surgery.

Claims 4, 13-17, 19-23, 25-36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hake. Hake shows all of the limitations of claims 4, 13-17, 19-23, 25-36 and 38 except for the specific offset angle, offset distance, and radius of curvature. Since the instant invention does not show criticality of a specific angle, distance, or radius of curvature, and the invention of Hake is capable of bending "in a desired direction," it would have been obvious to one of ordinary skill in the art at the time of the invention to bend the flexible tube at any angle, radius and distance.

Claims 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salerno. Salerno shows a method of using a probe in an intubation procedure, comprising the steps of: providing an endoscope with an elongate light guide having a flexible main portion and a distal end that is laterally offset from the flexible portion (col 5, lines 30-31); inserting the light guide into the mouth of the patient (col 5, lines 32-54) with the substantially rigid (col 3, lines 65-68) distal end offset in the direction of curvature; and advancing the light guide within the throat. Although Salerno teaches the placement of the endotracheal tube over the stylet, it would have been obvious to one of ordinary skill in the art at the time of the invention, that the stylet can also be inserted within an already placed intubation tube.

Response to Arguments

Applicant's arguments filed 5/6/03 have been fully considered but they are not persuasive. Regarding applicant's arguments of the Koyata reference, the examiner notes that the applicant has argued claims 6, 8, and 11, which were not rejected under Koyata. The reference numeral "5a" indicated by the applicant as mistakenly referring to the main portion was rather used by the examiner to indicated the offset distal end. The examiner has referred to the main portion as reference numeral "3". The applicant argues that the flexible tube (3) is not connected to the distal end (5), however the examiner respectfully disagrees (col 2, lines 41-43).

In response to applicant's argument that the "reason for the offset distal end if to prevent materials from being lodged in the distal end of the endoscope", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

The applicant states that the Hake reference does not show a main portion and a distal portion. The main portion and the distal portion are broad relative terms and are not distinctly separate components of the device, as broadly as claimed. Furthermore, although the series of connected segments (14) are continuous, each segment is distinct

in that the dimensions can differ and each segment is independently controllable (col 4, lines 16-21). Therefore the portions are not arbitrarily chosen by the examiner.

Additionally, any portion inherently has a proximal and distal end, and the distal end of the distal portion (14a) is offset from the main portion (14b, 14c).

In response to applicant's argument that the references (Salerno) fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., not being malleable) are not recited in the rejected claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). A flexible structure does include malleable guides that can be bent. Furthermore, Salerno does disclose a main portion and a distal portion as broadly as claimed, since these terms are relative and do not require that the main and distal portions have different properties

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Since the specific offset angle, offset distance, and radius of curvature lack

criticality and are in the range enabled by the structure of the devices of the references, the examiner contends that the obviousness rejection is proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jocelyn D Ram whose telephone number is (703) 308-6392. The examiner can normally be reached on Mon-Fri, 10-6.

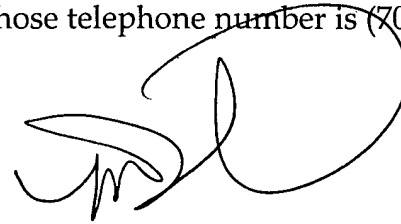
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (703) 308-0994. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 872-9302

for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to be 'LD', enclosed within a large, loopy oval shape.

LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700

JR
June 17, 2003